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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,647	07/07/2001	Dale R. Lovercheck	ANAL-VIT	6584

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/900,647	Applicant(s) LOVERCHECK, DALE R.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendments filed August 24, 2002 have been entered. The cancellation of claims 31 and 36 is acknowledged. The addition of claims 46 and 47 in amendments filed August 24, 2002 is acknowledged.

The outstanding rejections under 35 USC 112, second paragraph are withdrawn in view of the amendments filed August 24, 2002.

Claims 26-30, 32-35, and 37-47 are pending.

Warning

Applicant is advised that should claim 46 be found allowable, claim 47 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Please note that both claims are drawn to a method of indication comprising the same enclosing steps. The intended use of the composition employed in the enclosing steps does not lend patentable weight to the instant claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-35, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "functional discomfort reliever" recited in claim 32 renders the claims indefinite as to the compounds encompassed by the claims. It is not clear what compounds are considered as "functional discomfort reliever". Even though in the instant specification page 9, last paragraph to page 10, first paragraph, applicant attempts to define the term "functional discomfort reliever", it is not clear to one of ordinary skill in the art what compounds would be considered as "functional discomfort reliever" and what would not. It is because one of ordinary skill in the art would not know what "predetermined discomfort" would be. In the example disclosed in page 10, aspirin, also known as acetylsalicylic acid, is not considered as a "functional discomfort reliever", for the reason that is not clear to one of ordinary skill in the art: because aspirin "is not a predetermined amount of discomfort reliever initially and/or primarily adapted to function in relieving discomfort" (See page 10, first paragraph, last sentence). It is clear to one of ordinary skill in the art that aspirin is well-known to be useful in treating coronary heart disease (a predetermined discomfort). And therefore aspirin, or acetylsalicylic acid, should be considered as a "functional discomfort reliever".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-30, 32-35, and 37-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over SS Pharmaceutical (Comline Biotechnology & Medical, 1 Dec. 1992, page 4) in view of Tsunoda (JP 2000-229853, English abstract is also provided), Yeh et al. (US Patent 5,032,384), and Lambelet (US Patent 5,833,072).

SS Pharmaceutical teaches a composition containing ibuprofen and a high content of vitamin C (See the abstract).

SS Pharmaceutical does not expressly teach the composition as in unit dosage form. SS Pharmaceutical does not expressly teach the amount of ibuprofen and vitamin C as at least 50mg. SS Pharmaceutical does not expressly teach the composition is in an enclosure. SS Pharmaceutical does not expressly teach the composition is in an unit form as pill, tablet, or capsule. SS Pharmaceutical does not expressly teach the composition is package with an indicator indicating the amount of each ingredients and the indication.

Tsunoda teaches a pain-alleviating tablet containing 300-500mg of ibuprofen and about 30-50mg of vitamin C (See the abstract).

Yeh et al. teaches a composition containing an antioxidant, such as ascorbic acid, and a NSAID, such as ibuprofen, such that the weight amount of the antioxidant and the NSAID is about 0.01 to 10% of the composition (See particularly the abstract,

also col. 4, line 7-10). Yeh et al. also teaches that the composition can be formulated into oral dosage forms (See particularly col. 3, line 67).

Lambelet teaches a dosage regimen container with indicator, such as memory aid, for the drug delivery (See the abstract and col. 1, line 60 - col. 2, line 1; also claims 1-6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the amount of ibuprofen and vitamin C, as a unit dosage form, in the amount herein claimed into the composition claimed herein. It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the ibuprofen-vitamin C composition into tablet unit dose and enclose the same into a container with indicator indicating the amount of each ingredients and the indication.

One of ordinary skill in the art would have been motivated to employ the amount of ibuprofen and vitamin C in the amount herein claimed into the instant composition herein because the optimization of result effect parameters (e.g., dosage range) is obvious as being within the skill of the artisan, absent evidence to the contrary.

One of ordinary skill in the art would have been motivated to formulate the ibuprofen-vitamin C composition into tablet unit dose and enclose the same into a container with indicator because interconversion of dosage forms, such as from a multiple dosage form to unit dosage forms, would be obvious as being within the skill of the artisan, absent evidence to the contrary. Possessing the teachings of the cited prior art, the skilled artisan would reasonably expect enclosing the unit dosage in a package

or container with the indicator indicating the amount of each ingredients and the indication to be useful in formulating the ibuprofen-vitamin C composition. Furthermore, inclusion of a package insert or label showing the "indication and direction of use" of a pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, no data is disclosed in the specification for the evaluation of unexpected benefits. Therefore, no clear and convincing unexpected benefits are seen herein.

Response to Arguments

Applicant's arguments filed August 24, 2002 averring the cited prior art's failure to teach the intended uses recited in the claims herein have been fully considered but they are not persuasive. Please note the intended use (e.g., "the discomfort reliever not being adapted to aid in or contribute to nutrition supplementing", and "the nutritional supplement not being adapted to aid in or contribute to discomfort relieving") of the

components in the herein composition which is enclosed by the herein claimed method does not lend patentable weight. The instant method claims are drawn to a method comprising enclosing the herein claimed agents into an enclosure.

Applicant's arguments filed August 24, 2002 averring the cited prior art's failure to teach the herein claimed predetermined amount of ibuprofen and vitamin C have been fully considered but they are not persuasive. Absent showing of any criticality of the herein claimed amount, the optimization of result effect parameters (e.g., dosage range) is obvious as being within the skill of the artisan.

The two exhibits provided by the Applicant along with the amendments filed August 24, 2002 have been considered. Both references are shown to indicate that thiamine (also known as vitamin B1) is effective against pain. These two references are not seen to be relevant to the basis of the outstanding rejections under 35 USC 103(a) set forth in the previous office action mailed July 2, 2002.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
November 20, 2002

SREENI PADMANABHAN
PRIMARY EXAMINER

11/24/02